DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

December 19, 2014

Teleflex Medical
Ms. Ashlea Ricci
Senior Regulatory Affairs Specialist
2917 Weck Drive
Research Triangle Park, North Carolina 27709

Re: K142777
Trade/Device Name: Weck Auto Endo5 Hem-o-lok Ligating Clip Applier
Regulation Number: 21 CFR 878.4300
Regulation Name: Implantable Clip
Regulatory Class: Class II
Product Code: FZP
Dated: August 27, 2014
Received: September 26, 2014

Dear Ms. Ricci:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Binita S. Ashar -S

Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: K142777

Device Name: Weck® Auto Endo5® Hem-o-lok® Ligating Clip Appliers

Indications for Use:

The Weck Auto Endo5 Hem-o-lok ML automatic endoscopic ligating clip appliers are indicated for use as delivery devices for Hem-o-lok ML non-absorbable polymer ligating clips. These appliers are designed for use with 5/5.5mm cannulas.

Hem-o-lok Ligating Clips are intended for use in procedures involving ligation of vessels or tissue structures. Surgeons should apply the appropriate size clip for the size of the vessel or tissue structure to be ligated so that the clip completely encompasses the vessel or tissue structure.

Prescription Use **X** AND/OR **Over-the-counter use** __
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

 K142777

Teleflex®

510(k) SUMMARY

Weck® Auto Endo5® Hem-o-lok® Ligating Clip Applier

A. Name, Address, Phone and Fax Number of Applicant

Teleflex Medical, Incorporated
2917 Weck Drive
Research Triangle Park, NC 27709 USA
Phone: 919-433-8065
Fax: 919-433-4996

B. Contact Person

Ashlea Ricci, RAC
Senior Regulatory Affairs Specialist

Lorraine DeLong
Sr. Manager RA/QE Surgical

C. Date Prepared

August 27, 2014

D. Device Name

Trade Name:	Weck® Auto Endo5® Hem-o-lok® Ligating Clip Applier
Common Name:	Implantable Clip
Classification Name:	Clip, Implantable
Product Code:	FZP

E. Device Description

The Weck Auto Endo5 Hem-o-lok Ligating Clip Applier is an automatic, endoscopic applier that is pre-loaded with fifteen (15) Hem-o-lok medium-large, non-absorbable polymer ligating clips. The applier is a sterile, disposable device that is intended to be used by a surgeon or physician's assistant during laparoscopic procedures when ligation of vessels or tissue structures is necessary. The Auto Endo5 applier is actuated by a trigger, which is housed in a body assembly. Adjacent to the body is a turn knob that is used to rotate the applier jaws. The Auto Endo5 applier is 44 cm long with a working length of 29.7 cm. This applier can be used with a 5 or 5.5 mm cannula.

F. Indications for Use

The Weck Auto Endo5 Hem-o-lok ML automatic endoscopic ligating clip appliers are indicated for use as delivery devices for Hem-o-lok ML non-absorbable polymer ligating clips. These appliers are designed for use with 5/5.5mm cannulas.

Hem-o-lok ligating clips are intended for use in procedures involving ligation of vessels or tissue structures. Surgeons should apply the appropriate size clip for the size of the vessel to or tissue structure to be ligated so that the clip completely encompasses the vessel or tissue structure.

G. Contraindications

Hem-o-lok Ligating Clips are not intended for use as a contraceptive tubal occlusion device.

Hem-o-lok Ligating Clips are contraindicated for use in ligating the renal artery during laparoscopic donor nephrectomies.

H. Environmental Conditions

Hem-o-lok Ligating Clips are "MR Safe" and pose no known hazards in MR environments. This claim was cleared under K133202, December 30, 2013.

I. Substantial Equivalence

The proposed Weck Auto Endo5 Hem-o-lok Ligating Clip Applier is substantially equivalent to the predicate device:

Predicate Device	Manufacturer	510(k) No.	Date Cleared
Weck Hem-o-lok Automatic Ligating Clip Applier	Teleflex Medical (Weck Closure)	K021808	8/14/2002

J. Comparison To Predicate Devices

The proposed Weck Auto Endo5 Hem-o-lok Ligating Clip Applier has the same technology and functional characteristics as the predicate device. The modification proposed within this submission includes a change in the dry lubricant applied to various applier components.

K. Materials

All patient contacting materials, including those with indirect patient contact, are in compliance with ISO10993-1.

L. Technological Characteristics

A comparison of the technological characteristics of the proposed Weck Auto Endo5 Hem-o-lok Ligating Clip Applier and the predicate has been performed. The results of this comparison demonstrate that the Auto Endo5 applier is equivalent to the marketed predicate device.

M. Performance Data

Non-clinical performance testing has been conducted following product sterilization, aging, and simulated distribution in order to support a change to the dry lubricant applied to various applier components.

N. Conclusion

Based upon the comparative test results, the proposed Weck Auto Endo5 Hem-o-lok Ligating Clip Applier is substantially equivalent in performance to the predicate device cleared to market via 510(k) K021808. The modification made to the Auto Endo5 Ligating Clip Applier does not introduce any new issues of safety and effectiveness.